Gene therapy and cell therapy: regulation challenges faced by RNAs

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Advanced Therapy Products Regulation from the BRASIL's perspective

CELL THERAPIES

CONVENCIONAL THERAPY

- Blood Transfusion
- Haematopoeitc Reconstitution
- Tissues Transplantation
- Cells and tissues germinative for medicine reproductive

- ❑ Homologous use
- ❑ Minimum manipulated (no substantial)

ADVANCED THERAPY

- Gene Therapy
- Somatic-cell therapy
- Tissue engineering

- ❑ Substantially manipulated
- ❑ Non-homologous use

Advanced Therapy Products Regulation from the BRASIL's perspective

CONVENCIONAL THERAPY

Blood products or classical cell and tissue transplants - Specific regulations (authorized and licensed banks, GMP, standardized production, donor selection criteria, laboratory tests, etc)

Cell Therapy convencional

Clinical Trials – Approval by the Ethical Committees
Therapeutic use – Acknowledgement by the Medical or Dental Federal Councils
GMP Cells – specific regulations – Resolution Anvisa

Advanced Therapy Products Regulation from the BRASIL's perspective

National Cell Therapy Network

- Created in 2008
- 8 Cell Technology Centers

Financial Support: Ministry of Health and Ministry of Science and Technology of Brazil

Promotion of national scientific research

Advanced Therapy Products Regulation from the BRASIL's perspective

Advanced Therapy Products

LEGAL FRAMEWORK

- ✓ Standard for the approval of clinical trials
- ✓ Standard for the marketing authorization
- ✓ Standard for the Good Cell Practices

" regulatory model of biologics products"

Advanced Therapy Products Regulation from the BRASIL's perspective

Advanced Therapy Products

ANVISA in Cooperation with the Committee for Advanced Therapies-CAT

1- Developed in **clinical trials** from phase I/II to III authorized and monitoring by Anvisa

2- Assessed by Anvisa for obtaining **marketing authorization**

Advanced Therapy Products Regulation from the BRASIL's perspective

Advanced Therapy Products

ANVISA

3- Manufacture according to **GMP, certified by Anvisa** when intended to be administered to humans.

4- Post marketing requirement- BIOPHARMACOVIGILANCE (follow-up of efficacy/adverse reactions, risk management, traceability)

5- Establishment licensing/authorized by local regulatory authority

Thank you for your attention!
Gracias!
Obrigado!

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